**UNITED STATES DISTRICT COURT**

**FOR THE EASTERN DISTRICT OF TENNESSEE**

CHILDREN'S HEALTH DEFENSE and AMY MILLER, an individual,

Plaintiffs,

v.

FOOD & DRUG ADMINISTRATION, and JANET WOODCOCK, acting commissioner of Food & Drugs,

Defendants.

**Case No. 1:21-cv-00200**

**AMENDED COMPLAINT [F.R.C.P. Rule 15(a)(1)(A)]]**

District Judge Clifton L. Corker
Mag. Judge Christopher H. Steger

1. The FDA faced a conundrum: under immense political pressure to rush approval of a COVID-19 vaccine in record time to satiate the mandate fervor of some in the military and corporate America, the FDA acted -- without consulting its advisory board, without answering citizen petitions, without addressing scientific concerns, and even without updating its data regarding the Delta coronavirus variant. Knowing that approval and licensure of such a vaccine required revoking all Emergency Use Authorized vaccines for the same indication, and knowing that revocation would risk liability exposure to vaccine makers, government actors and healthcare workers, the FDA did the impermissible.

2. It answered this conundrum by pretending to "approve" a vaccine that isn't widely available, playing a game of bait-and-switch, and confusing the public into thinking they are getting a vaccine with some legal remedies when in fact they are not because of the bait-and-switch. The FDA purportedly managed to do what the law forbids: "approve" a vaccine but not revoke any Emergency Use Authorized vaccines for the same indication.

3. Plaintiffs Children's Health Defense (CHD) and Amy Miller bring this action

because the FDA is failing to carry out its mission. Plaintiffs seek this Court's intervention to put the FDA back on the path to lawful protection of the public in these precarious times.

## PARTIES

4. Plaintiff CHD is a not-for-profit membership organization incorporated under the laws of Georgia. Plaintiff sues in its own capacity and on behalf of its members who have been affected by Defendants' actions.

5. Plaintiff Amy Miller is resident of Hamilton County Co., TN, a member of CHD, and is at imminent risk of immediate harm from FDA's actions to both license and contemporaneously authorize Pfizer vaccines against COVID.

6. Defendant FDA is an agency within the U.S. Department of Health and Human Services.

7. Defendant Janet Woodcock, the Acting FDA Commissioner, is sued in her official capacity.

## JURISDICTION AND VENUE

8. This action arises out of Defendants' acts under 21 U.S. Code § 360bbb-3, Authorization for medical products for use in emergencies, and the Administrative Procedures Act, 5 U.S.C. § 500 *et seq*.

9. This lawsuit raises federal questions over which this Court has jurisdiction pursuant to 28 U.S.C. §§ 1331, 1361. This Court also has jurisdiction over this matter as complete diversity exists among the parties.

10. Pursuant to 28 U.S.C. § 1391(e), venue is proper in the Eastern District of Tennessee, where Plaintiff Amy Miller resides. Under 5 U.S.C. § 703, venue is proper in any court of competent jurisdiction.

11. An actual and justiciable controversy exists between Plaintiffs and Defendants.

## STATEMENT OF FACTS

12. On January 31, 2020, Alex M. Azar, II, the Secretary of Health and Human Services, declared a public health emergency as of January 27, 2020, pursuant to § 319 of the Public Health Service Act, 42 U.S.C. § 247d *et seq*.

13. Section 564 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 360bbb-3, authorizes the FDA to issue an Emergency Use Authorization (EUA) for a vaccine under certain emergency circumstances, allowing a vaccine to be introduced and administered to the public even when the product has not gone through the review process necessary for approval and licensure.

14. In an emergency, the Secretary of Health and Human Services may issue EUAs if he concludes that the following facts exist: (1) a serious or life-threatening disease; (2) a product "may be effective" in treating or preventing it; (3) "no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;" (4) a risk-benefit analysis that measures both the known and potential benefits of the product against the known and potential risks of the product is positive; and (5) that the patient's option to accept or decline the product is protected through informed consent. 21 U.S.C. § 360bbb-3(c)(1)-(5).

15. On December 11, 2020, the FDA issued an EUA for use of Pfizer-BioNTech COVID-19 Vaccine to prevent COVID-19 for individuals 16 years of age and older pursuant to Section 564 of the Act.

16. The FDA issued EUAs to Pfizer even though its Phase III clinical trials even now remain incomplete. Pfizer's clinical trial Estimated Primary Completion Date is November 2, 2022, and the Estimated Study Completion Date is May 2, 2023. *See Study to Describe the*

*Safety, Tolerability, Immunogenicity, and Efficacy of RNA Vaccine Candidates Against COVID-19 in Healthy Individuals*, CLINICALTRIALS.GOV, https://clinicaltrials.gov/ct2/show/NCT04368728

17. CHD filed a Citizen Petition with the FDA (Exh. 1) on May 16, 2021, asking the FDA to refrain from licensing COVID vaccines and to revoke EUAs for the three existing COVID vaccines. Individuals have submitted over 30,000 comments on this petition. https://www.regulations.gov/document/FDA-2021-P-0460-0001

18. Pam Long, a former Army officer, Ssgt Samuel Craymer, a current servicemember in the US Air Force, LT John Eschmann, a current servicemember in the US Navy, AE1(AW) Wayne Hastriter, a current servicemember in the US Navy, 2d Lt Cassidy Hollowell, a current servicemember in the US Air Force, TSgt Nathaniel Mason, a current servicemember in the Air National Guard, MSgt Thomas Meacham, a current servicemember in the US Air Force Reserve, Sgt Jake Nuss, a current servicemember in the US Army, CW2 Robert Perez, a current servicemember in the US Army, MSgt Steven Raethel, a current servicemember in the US Air Force, SPC Christopher Santos, a current servicemember in the US Army, LT Jonathan Shour, a current servicemember in the US Navy, Gunnery Sergeant John Stanzione, a current servicemember in the US Marine Corps, CDR Joseph Sweger, a current servicemember in the US Navy, and LCDR Mark Zito, a current servicemember in the US Navy, are active members of CHD as of the filing of this action and have provided declarations on behalf of the organization in this action [Doc. No. 15].

19. Pfizer announced on July 16, 2021 that FDA granted Priority Review designation for the Biologics License Application (BLA) for its mRNA vaccine to prevent COVID-19 in individuals 16 years of age and older. The announcement noted that the FDA had expanded the

EUA of the Pfizer-BioNTech COVID-19 vaccine to include individuals 12 years of age and older. (Exh. 2)

20. On August 23, 2021, the FDA granted a license to Pfizer's "Comirnaty" vaccine (Exh. 3) and extended the EUA for its Pfizer-BioNTech vaccine. In its letters to Pfizer and BioNTech, the FDA acknowledged that Pfizer's vaccines are "interchangeable" yet "legally distinct." (Id. at Ftn. 8) It further stated: "The licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably... The products are legally distinct with certain differences that do not impact safety or effectiveness."

21. The FDA also responded to CHD on August 23, 2021, the same day it granted the license to Pfizer's Comirnaty and extended the EUA for Pfizer-BioNTech vaccine. (Exh. 4)

22. Although Defendant Janet Woodcock is the acting commissioner, the fact that she did not sign the Pfizer's licensure and EUA extension (Exh. 4), she still bears responsibility for the FDA's actions as pled herein.

23. FDA failed to convene its outside expert panel to deliberate on the Pfizer Comirnaty licensure. FDA asserted in its licensure letter to Pfizer: (Exh. 5 Page 2)

> We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in you BLA, including the clinical study design and trial results, **did not raise concerns or controversial issues** that would have benefited from an advisory committee discussion. (emphasis added)

24. FDA deliberately misleads the public by confusing the words approval (implying licensure) and authorization (not licensed). "The EUA will continue to cover adolescents 12 through 15 years of age and the administration of a third dose to certain immunocompromised individuals 12 years of age and older. Additionally, for logistical reasons, the EUA will continue to cover the use of the Pfizer-BioNTech COVID 19 Vaccine in individuals 16 years of age and older; this use is also now approved." (Exh. 6)

25. The EUA shields manufacturers from liability for both "[a]n unapproved drug, biological product, or device used under an Emergency Use Authorization (EUA) issued by FDA; or [a]n approved drug, biological product, or device used pursuant to Federal law in conditions that are inconsistent with its approval." (Exh. 7)

26. FDA's representation that licensure of its Comirnaty vaccine does not "raise concerns or controversial issues" (Exh. 5 Page 2) is transparently false. Although Janet Woodcock and the FDA have gone to great lengths to obscure its subversion of law, their actions speak for themselves.

## ARGUMENT

27. FDA's actions to simultaneously license Pfizer's "Comirnaty" vaccine and to extend Pfizer's EUA for its vaccine that has the "same formulation" and that "can be used interchangeably" violates federal law. (Exh. 3)

28. The law on "Authorization for medical products for use in emergencies" requires that the EUA designation be used only when "**there is no adequate, approved, and available alternative** to the product for diagnosing, preventing, or treating such disease or condition." 21 U.S. Code § 360bbb-3-(3) (emphasis added).

29. Once FDA approved and licensed Pfizer's Comirnaty vaccine, there was no further basis for the FDA to preserve the EUA status for the Pfizer-BioNTech vaccine that Pfizer acknowledges has the "same formulation" and is "interchangeable."

30. There also is no basis to retain EUA status for other COVID vaccines for the same use and for the same population as Pfizer's Comirnaty vaccine. FDA's decision to evade these requirements is arbitrary and capricious.

31. The FDA has failed to abide by its own criteria for EUA designation; its decision

must be vacated and remanded.

32. The Administrative Procedures Act (APA) protects the public from arbitrary and capricious executive branch action by imposing the rule of reason and the rule of law through judicial oversight. An agency is "required to engage in reasoned decision making." *Michigan v. EPA*, 576 U.S. 743, 750 (2015). This requires that the agency "articulate a satisfactory explanation for its action." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983).

33. This agency process requires Defendants to articulate clear rationales for decisions, especially when their actions are bound to lead to a medical mandate for millions of people. *Burlington Truck Lines v. United States*, 371 U.S. 156, 158 (1962).

34. When courts abandon this standard of oversight, the public is at grave risk. If pressure from politicians and profiteers rush regulators to license a biologic and violate the law, debacles predictably unfold and tragedies result.

35. A "reasonable time for agency action is typically counted in weeks or months, not years," *In re Am. Rivers & Idaho Rivers United*, 372 F.3d 413, 419 (D.C. Cir. 2004), and an agency action's exigent context may demand expedited review. *Fund for Animals v. Norton*, 294 F.Supp.2d 92, 114 (D.D.C. 2003) ("pressing human health concerns…demand prompt review").

36. Congress requires that courts "shall hold unlawful and set aside" any agency "action," "finding," or "conclusion" whenever the agency failed to follow the necessary process for reasoned decision-making. 5 U.S.C. 706(2)(A).

37. *University of Cincinnati v. Shalala*, 891 F. Supp. 1262, 1269-1270 found that [u]nder this arbitrary and capricious standard, the court must determine "whether the agency decision was based on a consideration of the relevant factors and whether there has been a clear

error in judgment." Motor Vehicle Mfrs. Assn. v. State Farm Mutual Auto, Ins. Co., 463 U.S. 29, 43, 77 L. Ed. 2d 443, 103 S. Ct. 2856 (1983). This standard of review is narrow; however, notwithstanding, "the agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" Id. (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168, 9 L. Ed. 2d 207, 83 S. Ct. 239 (1962)). If the agency's interpretation is reasonable, the court must uphold it even if the court would have reached a different interpretation had that issue first been presented to it. *Tallman*, 380 U.S. at 16. However, the court must reject administrative constructions that are inconsistent with a statutory mandate, frustrate congressional policy, or, otherwise, not supported by "substantial evidence on the record considered as a whole." *Federal Election Com. v. Democratic Senatorial Campaign Committee*, 454 U.S. 27, 29-33, 70 L. Ed. 2d 23, 102 S. Ct. 38 (1981); See also *State Farm Mutual Auto. Ins. Co.*, 463 U.S. at 44.

38. By flagrantly violating federal law, the FDA has failed to follow reasoned decision-making. Pfizer cannot unlawfully reap the benefits of licensure and EUA status simultaneously, even if the FDA says it can. This clearly violates Congress' intent regarding emergency medical countermeasures.

39. The FDA has indulged Pfizer to "have it both ways." Pfizer now enjoys the imprimatur of safety, effectiveness and legality from a license while retaining the blanket liability shield of an EUA product.

40. The documents the FDA made public regarding these decisions contain tortured, barely comprehensible language that fails to explain the "legally distinct" differences between the Pfizer vaccines with differing labels and designations. How can vaccines under EUA and license be "interchangeable" yet "legally distinct?" (Exh. 3 Ftn. 8)

41. This linguistic smokescreen almost certainly conceals the fact that the available EUA product, Pfizer-BioNTech, has a priceless PREP Act liability shield (Exh.7) while the unavailable, licensed vaccine, Comirnaty, does not rightfully have that shield.

42. Once the FDA licensed the Comirnaty vaccine for those 16 and older, it was legally obliged to revoke the EUAs for the other COVID vaccines for this age group. Yet it failed to do so.

43. The new Comirnaty vaccine cannot also be authorized for emergency use for the first two doses of vaccines in adults since this is its licensed indication. The Pfizer Comirnaty vaccine should be subject to ordinary product liability when used for the first two doses of the vaccine for adults.

44. Coverage under the Vaccine Injury Compensation Program, which will eventually afford the Comirnaty vaccine substantial liability protection, only occurs when (1) the vaccine is recommended by the Centers for Disease Control and Prevention for routine administration to children and/or pregnant women; (2) Congress enacts an excise tax on the vaccine; and (3) the Department of Health and Human Services adds the vaccine to the Vaccine Injury Table through publication of a notice of coverage in the *Federal Register*. https://www.hrsa.gov/vaccine-compensation/covered-vaccines/index.html.

45. The FDA is creating legal cover for licensed vaccine mandates while gifting Pfizer a bullet-proof liability shield that comes only with an EUA. It has tried to please two masters: the Executive Branch, which has insisted on licensed vaccines for pervasive mandates, and Pfizer, which demanded indemnification from any vaccine-related injuries and deaths. But the FDA seems to have forgotten its one true client: the American public.

46. While FDA may argue that Pfizer's Comirnaty vaccine is currently unavailable in

the United States, and thus it is not in violation of the law as the licensed alternative must be "available," this argument is specious. Pfizer's Comirnaty vaccine is its primary product in Europe; if its two "interchangeable" vaccines are truly so, then Pfizer can relabel its EUA Pfizer-BioNTech vials with Comirnaty labels or vice versa.

47. FDA makes excuses for Comirnaty's lack of availability in its August 23, 2021 letter to Pfizer, stating that "there is not sufficient approved vaccine available for distribution to this population in its entirety at the time of reissuance of this EUA." (Exh. 3 Ftn. 9)

48. Either Pfizer's vaccine for those 16 and up is licensed or it's not; either it's EUA, or it's not. It clearly contradicts the law for this product to be both licensed and authorized simultaneously. Such trickery undermines the public's confidence in the FDA when it so desperately needs to have that trust. The FDA's actions also undermine the rule of law.

49. The FDA has arbitrarily and capriciously allowed Pfizer to play "bait and switch": to represent that Pfizer vaccines are licensed and available while selling off its inventory of experimental vaccines that enjoy blanket liability protection. These FDA actions are arbitrary, capricious and illegal.

50. The FDA's licensure of the Pfizer Comirnaty vaccine triggered employer, military, educational and institutional mandates across the country, coercing millions of healthy individuals to take unwanted, risky medical interventions.

51. These mandates are creating myriad economic dislocations, including in healthcare, education and law enforcement. Millions will be forced out of jobs and institutions rather than submit to potentially injurious medical interventions.

52. While the finding of "arbitrary and capricious" agency action is a high bar, and courts are appropriately reluctant to second guess administrative action, there are times when

justice demands judicial action. Now is such a time.

## CAUSE OF ACTION

### Failure to Abide by Federal Law as Abuse of Discretion -- APA 5 USC 706 (2) (A)

53. Plaintiffs incorporate the foregoing paragraphs as if fully set forth herein.

**The FDA's Licensure of Pfizer's Comirnaty Vaccine is Arbitrary and Capricious**

54. An agency's action is "arbitrary and capricious" if it did not articulate any rational connection between the facts it found and the choices it made. *Burlington Truck Lines v. United States*, 371 U.S. 156, 168. The FDA's action failed to articulate a lawful rationale.

55. Defendants authorized the Comirnaty vaccine to give the misleading impression to the public that the vaccine that would be mandated is fully approved, when in fact what is available, according to the FDA's own admission is actually the EUA, liability-free product.

56. Politics and industry pressure should play no role in the approval and authorization process, yet they appear to have been central in the FDA's decision-making process.

57. Defendants acted arbitrarily and capriciously by failing to engage in a pluralistic, critical, open, transparent and scientific dialogue with the public and medical community based on careful, deliberative evaluation of all relevant research before rushing the approval of this vaccine.

58. Defendants' arbitrary and capricious actions warrant vacatur and remand.

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## PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Amy Miller and Children's Health Defense respectfully ask this Court:

i. To vacate and remand the FDA's decision to license Pfizer's Comirnaty vaccine and to extend its Pfizer-BioNTech Emergency Use Authorization;

ii. To award attorneys' fees and costs, as authorized under 28 U.S.C. 2412; and

iii. To grant all other appropriate relief as necessary.

Dated: September 23, 2021

Respectfully submitted,

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